

Safety Alert

May 2024

Azacitidine– Risk of Cutaneous vasculitis

EDA performs label update to include the following:

4. CLINICAL PARTICULARS

4.8 Undesirable effects

System Organ Class

Not Known

Skin and subcutaneous tissue disorders

Cutaneous vasculitis

Background:

Therapeutic Indication

Azacitidine is indicated for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (HSCT) with:

- Intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS),
- Chronic myelomonocytic leukaemia (CMML) with 10-29 % marrow blasts without myeloproliferative disorder,
- Acute myeloid leukaemia (AML) with 20-30 % blasts and multilineage dysplasia, according to World Health Organisation (WHO) classification,
- AML with >30% marrow blasts according to the WHO classification.

References:

EMA ([Click here](#))